From: William Johnson [contact@netprofitnow.com]
Sent: Monday, January 10, 2005 3:30 PM
To: Dockets, FDA
Subject: Docket No. 2004D-0369

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January 10, 2005

FDA Dockets
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Dear FDA Dockets:

My comments are for Docket No. 2004D-0369 regarding the FDA's "Draft Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use; Availability."

I object to the policy outlined in the Draft Guidance for Industry. It is essentially permitting the continued contamination of our food and seed supply with genetic material from thousands of biotech crop experiments. And it fails to address the major shortcomings of the FDA's regulation of crops produced through biotechnology.

The FDA acted irresponsibly in 1992 when it initially addressed the safety evaluation of genetically engineered crops and determined them to be "substantially equivalent" to non-genetically engineered crops. Genetically engineered crops contain antibiotic-resistant marker genes, viral promoters and foreign proteins never before consumed by humans. These factors are not found in crops produced through normal means of hybridization. These crops are NOT "substantially equivalent" and it is beyond common logic to represent them with this status.

Rather than recognizing and dealing responsibly with the shortcomings of your initial 1992 determination, the FDA is continuing to jeopardize the safety of the American public by attempting to fine-tune your flawed regulatory scheme.

Under current FDA regulations, a biotech company bringing out a new product is not even required to notify your agency. Even though companies have notified the FDA until this point, there is no guarantee that they will continue to do so on an ongoing basis. The lack of a mandatory notification requirement leaves the door open for a wide range of abuses at any point in the future. These abuses could run the gamut from mischievous behavior, to negligence, to deliberate acts of terrorism in an attempt to contaminate the American food supply.

Further, the voluntary review process outlined in the Draft Guidance for Industry is most likely inadequate to actually determine potential problems. The proposed review does not involve safety tests in animals, and it excludes testing for unintended effects caused by genetic engineering. It also sets no limits on the amount of contamination allowed in foods.

The FDA approach to regulating genetically engineered foods appears to be designed to promote the biotech industry rather than protect the health of

the American public. Rather than protecting the food supply, this Draft Guidance for Industry appears to be designed to provide biotech companies with legal cover for contaminating the food supply with experimental biotech traits.

We only need to look at the contamination of the food supply from StarLink corn a few years ago to get evidence that the FDA has shirked it responsibilities. Why was it that the problem with the digestibility of the protein contained in StarLink corn was discovered by the Environmental Protection Agency rather than the FDA? The answer is that your agency wrote yourselves out of an adequate review process with your "substantially equivalent" and voluntary notification guidelines.

And perhaps it would be worthwhile to remind the FDA that it was the non-profit organization Friends of the Earth who discovered the contamination of the American food supply with StarLink corn. If Friends of the Earth had not discovered the contamination, StarLink corn may still be in the U.S. food supply causing allergic reactions in thousands of unsuspecting citizens.

The FDA's policy for regulating genetically engineered crops is broken and needs a major overhaul. The band-aid approach that this Draft Guidance for Industry provides is totally inadequate.

The FDA needs to develop an entirely new policy for regulating crops produced through agricultural biotechnology. The new policy should include the following requirements:

1) mandatory labeling of all genetically engineered foods
2) mandatory safety testing of recombinant-DNA plants similar to what is required for a new drug or food additive 3) all biotech crop experiments should be conducted in greenhouses or similar controlled environments

Only when the FDA adopts these three policy requirements will the public be able to rest assured that biotechnology-derived plants will not cause health problems and the contamination of the American food supply.

Sincerely,

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Owner
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